

Message

**From:** Jones, Samantha [Jones.Samantha@epa.gov]  
**Sent:** 4/21/2015 2:38:29 PM  
**To:** D'Amico, Louis [DAmico.Louis@epa.gov]  
**Subject:** my thoughts on the BNA SAB BaP article

I think this is fair summary of comments made at the meeting. While she quoted particularly more critical statements, I do recall these being said. It would have been nice to have my response about the need for dermal guidance.

I like how she quoted (likely the guy from USWAG) about the particular things he is going to look for in the report.

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**From:** Bland, Naseera

**Sent:** Tuesday, April 21, 2015 9:52 AM

**To:** Alcalá, Cecilia; Alexander, Laurie; Avery, James; Bateson, Thomas; Berner, Ted; Birchfield, Norman; Bland, Naseera; Blessinger, Todd; Boone-Edwards, Amanda; Brinkerhoff, Chris; Buckley, Barbara; Burgoon, Lyle; Bussard, David; Cai, Christine; Carmichael, Brenda; Choudhury, Harlal; Coglianò, Vincent; Corona, Elizabeth; Cubbison, Christopher; CURTIS, LUCY; D'Amico, Louis; Deener, Kathleen; Euling, Susan; Evans, Amanda; Field, Malcolm; Fite, Katherine; Flowers, Lynn; Frithsen, Jeff; Fritz, Jason; Galizia, Audrey; Gamble, Janet; Gatchett, Annette; Gibbons, Catherine; Glenn, Barbara; Grambsch, Anne; Gwinn, Maureen; Haque, Mefruz; Hawkins, Belinda; Hogan, Karen; Hotchkiss, Andrew; Iuliano, Kayla; Jarabek, Annie; Jinot, Jennifer; Johnson, Maureen; Jones, Samantha; Kadry, Abdel-Razak; Keshava, Nagalakshmi; Kopylev, Leonid; Kraft, Andrew; Lee, Janice; Lin, Yu-Sheng; Long, Tom; Luke, April; Makris, Susan; Murphy, Patricia; Nath, Raghu; Newhouse, Kathleen; Olden, Kenneth; Owens, Beth; Pardo, Larissa; Perovich, Gina; Persad, Amanda; Petersen, Dan; Powers, Christina; Pratt, Margaret; Preuss, Peter; Reid, Jon; Rieth, Susan; Ross, Christine; Ross, Mary; Rutigliano, Marian; Salazar, Matt; Sams, Reeder; Samuels, Crystal; Sanchez, Yolanda; Sasso, Alan; Schappelle, Seema; Schlosser, Paul; Segal, Deborah; Shams, Dahnish; Shaw, Denise; Slimak, Michael; Sonawane, Bob; Spassova, Maria; Suter, Glenn; Taylor, DebraLynn; Troyer, Michael; Vandenberg, John; Vinikoor-Imler, Lisa; Vulimiri, Suryanarayana; Walker, Teneille; Walsh, Debra; Weaver, Andre; White, Paul; Woodall, George; Wright, Michael; Yang, Hui-Min; Zwayer, Bette  
**Subject:** News Update: Risk Values for Key Combustion Chemical Need More Work, EPA Science Advisers Say (BNA)

***Risk Assessment***  
**Risk Values for Key Combustion Chemical  
Need More Work, EPA Science Advisers Say**



**BNA Snapshot**

**Benzo[a]pyrene Proposed Risk Values**

**Key Development:** Proposed risk values that the EPA would use as it develops hazardous waste cleanup standards, air and possibly other regulations managing risks from polycyclic aromatic hydrocarbons need more work before they can be used, agency advisers say.

**What's Next:** The advisers will hold public meetings Aug. 21 and Sept. 2 to finish their recommendations, which must be reviewed by the full Science Advisory Board before being submitted to the agency.

*By Pat Rizzuto*

April 20 — Proposed risk values that the Environmental Protection Agency would use as it develops hazardous waste cleanup standards, air standards and possibly other regulations managing risks from polycyclic aromatic hydrocarbons (PAHs) need more work before they can be used, a panel of agency advisors said April 17.

The EPA's Chemical Assessment Advisory Committee met April 15-17 to peer review a draft Integrated Risk Information System (IRIS) assessment the agency prepared for benzo[a]pyrene (CAS No. 50-32-8), which is produced by incomplete combustion and found at many Superfund sites.

In a draft assessment issued in 2013 and updated in 2014, the EPA concluded benzo[a]pyrene is a human carcinogen that also harms development, the immune system and reproduction (193 DEN A-6, 10/6/14). The committee generally concurred with the health hazards the EPA identified and suggested it explore whether benzo[a]pyrene might cause additional problems, including cardiovascular ones. The committee, however, questioned a number of the risk values, or dose-response calculations, the agency proposed. The risk values described lifetime oral or inhalation doses of benzo[a]pyrene that the agency estimated people could experience without harm from effects other than cancer, and they describe the carcinogenic potency of benzo[a]pyrene.

### **Most-Studied of PAHs Compounds**

The agency's eventual conclusions about benzo[a]pyrene are important because it is the most-studied compound of the family of more than 100 PAHs, which are produced when coal, oil, wood, garbage and other materials are burned but the combustion process isn't complete.

People also can be exposed to PAHs by eating barbecued or smoked foods or by applying coal tar-based medications used for skin problems such as eczema. Benzo[a]pyrene is called an index chemical because information about it is used to evaluate risks from other PAHs.

The EPA's air office will use risk values, health effects conclusions and other information in a toxicological review of benzo[a]pyrene to make at least a dozen decisions, an agency toxicologist told the committee April 15.

During the public comment session, consultants also said the agency's conclusions would affect hazardous waste cleanup standards (73 DEN A-11, 4/16/15).

### **Science to Estimate Skin Cancer Potency Unclear**

"The state of the science is not entirely clear," committee member Alan Stern said.

Stern, who manages the risk assessment section of New Jersey's Department of Environmental Protection, commented on the state of scientific knowledge that the EPA could draw upon to estimate the IRIS program's first attempt to calculate a risk value to predict the skin cancer potency of a chemical.

The risk value, called a dermal slope factor, that the EPA proposed for benzo[a]pyrene was 0.006 microgram per day ( $\mu\text{g}/\text{d}$ ). The factor would mean benzo[a]pyrene is a potent cause of skin cancer.

Concerns about the dermal slope factor and allegations that it greatly exaggerated benzo[a]pyrene's skin cancer-causing potential prompted more public comment during the committee's meeting than did any other single aspect of the draft IRIS assessment.

The comments came from trade associations, including the American Petroleum Institute, the Asphalt Institute, the Electric Power Research Institute and the Utility Solid Waste Activities Group.

### **Uncertainties in Calculating Potency Value**

Advisory committee members discussed many uncertainties they had about how the agency would calculate a potency value.

Due to those uncertainties, committee members said they couldn't recommend specific methods the agency should use to calculate the dermal slope factor.

"We don't have a consensus on how [the agency should] move forward," committee member Sean Hays, president of the consulting firm Summit Toxicology, said.

The committee did agree, however, that the agency should provide a logical line of reasoning to explain whatever choices it makes.

"EPA hasn't presented an underlying logical structure to explain its dermal slope factor, and it needs a logically coherent underpinning," Stern said.

### **EPA Urged to Keep Developing Dermal Data**

"We want EPA to keep developing dermal information," said Elaine Faustman, who chaired the committee.

"We want risk numbers EPA can use to protect children," said Faustman, who directs the University of Washington's Center for Child Environmental Health Research.

The committee's report will list scientific questions the agency should consider if it proceeds to develop a dermal slope factor, Faustman said.

The committee also raised concerns about draft risk values the agency had calculated for inhaled benzo[a]pyrene.

William Michael Foster, a pulmonary researcher who recently retired from Duke University, was among the committee members who urged the agency to consider whether occupational studies of PAH-exposed workers could provide a stronger basis to predict the cancer-causing potency of inhaled benzo[a]pyrene.

### **Inhalation Unit Risk**

The inhalation cancer potency rate, called an inhalation unit risk, was 0.000002 microgram per cubic meter of air ( $\mu\text{g}/\text{m}^3$ ). The EPA based that estimate on the results of a toxicity study in which male hamsters inhaled BaP.

The committee also urged the agency to see if it could expand the number of studies used to calculate its reference concentration (RfC), a lifetime dose that could be inhaled without harm from problems other than cancer. The agency based its draft RfC of 0.000002 milligram of benzo[a]pyrene per cubic meter of air on a rat study that found fewer pups born to exposed dams.

"Fetal death is relevant," said committee member Barry McIntyre, a senior toxicologist working at the National Toxicology Program. The agency's draft assessment mentioned two other studies that might provide more information, or "the database may be so weak that derivation of an RfC is not possible," he said.

### Next Steps

The committee will hold two public teleconferences to complete its report, which then must be reviewed by the agency's full Science Advisory Board before being given as formal recommendations to the agency. The dates for those teleconferences are Aug. 21 and Sept. 2. The SAB staff office, which acts as a secretariat for the committee, will post the committee's draft report critiquing the agency's draft benzo[a]pyrene assessment about one month before the August teleconference. Trade associations will review that draft to identify several aspects, a consultant told Bloomberg BNA April 20. He asked not to be identified because the trade association for which he is tracking the benzo[a]pyrene assessment had not reviewed his comments.

### Issues to Be Reviewed

These issues include:

- how strongly, or not, the committee recommends the agency issue a dermal slope factor;
- how many and which issues the committee recommends the agency consider if it does calculate a dermal slope factor for benzo[a]pyrene; and
- what recommendations it makes about the EPA developing overarching guidance on how to develop dermal slope factors.

Faustman said the committee needed more guidance as to how the agency had calculated its benzo[a]pyrene dermal slope factor.

Anne LeHuray, executive director of Pavement Coatings Technology Council, told the committee that until the agency develops overall guidance on the development of these skin cancer potency values, the EPA should not issue one for benzo[a]pyrene specifically.

To contact the reporter on this story: Pat Rizzuto in Washington at [Ex. 5 Deliberative Process (DP)]

To contact the editor responsible for this story: Larry Pearl at [Ex. 5 Deliberative Process (DP)]

### For More Information

EPA and public presentations made at the benzo[a]pyrene committee meeting are available at <http://tinyurl.com/pjjk2eb>, which also has links to the agency's draft assessment.

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C: [Ex. 6 Personal Privacy (PP)]